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No. 06-1249

In the Supreme Court of the United States

WYETH,

Petitioner,

v.

DIANA LEVINE,

Respondent.

On Writ of Certiorari to the Supreme Court of Vermont

BRIEF OF *AMICUS CURIAE* PRODUCT LIABILITY ADVISORY COUNCIL, INC., IN SUPPORT OF PETITIONER

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BRIEF OF PRODUCT LIABILITY ADVISORY COUNCIL, INC., AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF THE *AMICUS CURIAE*

Product Liability Advisory Council, Inc. ("PLAC") is a non-profit association with 121 corporate members representing a broad cross-section of American and international product manufacturers. These companies seek to contribute to the improvement and reform of the law in the United States and elsewhere, with an emphasis on the law governing the liability of manufacturers of products. PLAC's perspective is derived from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. Since 1983, PLAC has filed over 825 briefs as *amicus curiae* in both state and federal courts, including this Court, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product liability. A list of PLAC's corporate members is attached as Appendix A.[1]

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[1] Petitioner has filed a letter giving blanket consent to the filing of *amicus* briefs in this case; respondent's letter consenting to the filing of this brief has been filed with the clerk. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

PLAC—which filed *amicus* briefs in prior preemption cases including *Geier* v. *American Honda Motor Co.*, 529 U.S. 861 (2000), and *United States* v. *Locke*, 529 U.S. 89 (2000)—is well situated to address the issue of preemption raised in this case. PLAC's members are engaged in commerce in each of the 50 states and are subject in varying degrees to a wide range of federal regulations. Consequently, PLAC's members have often confronted the interplay between the duties imposed by federal law and the state common-law standards applied in product liability cases. Therefore, PLAC not only is uniquely suited to offer a broader perspective on preemption than the parties may provide, but it also is keenly interested in ensuring that the regulatory environment in which its members operate is a rational and consistent one.

INTRODUCTION AND SUMMARY OF ARGUMENT

The time has come for this Court to clarify once and for all that—contrary to the opinion below—the presumption against preemption simply does not apply to the analysis of whether state law conflicts with federal law. Although this Court has at times invoked the presumption when analyzing claims of *field* preemption and *express* preemption (albeit inconsistently and controversially), it almost never has done so when addressing claims of *conflict* preemption. Moreover, in recent decisions involving conflict preemption, the Court—by emphasizing ordinary principles of statutory interpretation and the inapplicability of any additional burdens prior to a finding of preemption—has clearly, albeit implicitly, signaled that the presumption indeed has

no role in conflict preemption analysis. It is time to make the implicit explicit.

Foundational and long-recognized principles of constitutional law and statutory construction fully justify not applying the presumption when engaging in conflict preemption analysis. As a preliminary matter, there is no textual basis in the Constitution for applying such a presumption in any circumstance, and, although never addressed by the Court, there are serious problems with the "federalism concerns" that have been invoked to justify the presumption. Furthermore, conflict preemption is fundamentally different from field and express preemption—the strands of preemption doctrine in which the Court traditionally has applied the presumption—in that conflict preemption analysis does not require a court to infer Congress's preemptive intent. Determining whether there is an actual conflict between state and federal law instead requires a judicial interpretation of the substantive—as opposed to the preemptive—meaning of a statute. As this Court's decisions indicate, such substantive interpretation does not implicate the presumption. Once an actual conflict has been identified as a matter of substantive law, a finding of preemption follows inescapably from the Supremacy Clause.

The Vermont Supreme Court, influenced by its mistaken application of the presumption against preemption, erroneously concluded that respondent's state-law tort claims do not conflict with federal law. Although this case arises in the context of federal drug regulation, its significance extends far beyond the pharmaceutical industry. If the decision below is allowed to stand, all manufacturers of federally

regulated products will be at risk of having to choose between complying with federal law or complying with state law. If they decide to comply with federal law, they will—like petitioner in this case—be exposed to multimillion dollar state-law tort liability. No company should be forced to make that choice or to suffer those consequences.

In addition to being fundamentally unfair, the decision below impedes interstate commerce and threatens the proper functioning of the federal regulatory system. In allowing private litigants to hold manufacturers liable under state law for failing to include risk warnings that are contrary to those mandated by the Food and Drug Administration, the Vermont Supreme Court—expressly disregarding the agency's views—misconstrued federal statute and misapplied this Court's precedent. In particular, the Vermont Supreme Court misinterpreted the meaning of a savings clause and disregarded this Court's teachings on the scope of conflict preemption. The results—both direct and indirect—are potentially devastating. Permitting juries in individual cases to substitute their *ad hoc* conclusions for those reached by an expert federal agency can easily upset the delicate regulatory balance struck by that agency after comprehensive review and careful consideration of all available scientific information. By undermining the Supremacy Clause, the decision below not only thwarts federal pharmaceutical policy, but threatens the efficacy of federal policy in other, similarly regulated industries.

ARGUMENT

I. The Presumption Against Preemption Is Inapplicable To Conflict Preemption Analysis.

This Court's recent case law, as well as established principles of constitutional law and statutory construction, provide strong grounds for concluding that the presumption against preemption has no application in the judicial determination of whether preemption is necessary because of an "actual conflict" between state and federal law. *Geier* v. *Am. Honda Motor Co.*, 529 U.S. 861, 884 (2000).[2] Accordingly, the Court should end years of ambiguity and avoidance of this question and clarify that a court may not invoke the presumption when analyzing claims of conflict preemption.

A. This Court's recent decisions indicate that the presumption against preemption does not apply to conflict preemption analysis.

As a general matter, the Court's adherence to the presumption against preemption—usually described as a requirement that Congress make its preemptive intent "clear and manifest" "[i]n areas of traditional state regulation," *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) (internal quotation marks omitted); see also *Medtronic, Inc.* v. *Lohr*, 518 U.S.

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[2] An "actual conflict" exists (i) where it is impossible for a private party to comply with both state and federal requirements, or (ii) where state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress. See, *e.g.*, *English* v. *Gen. Elec. Co.*, 496 U.S. 72, 79 (1990).

470, 485 (1996)—has been inconsistent and controversial. The Court's earliest Supremacy Clause cases made no mention of such a presumption. See, *e.g.*, *Martin* v. *Hunter's Lessee*, 14 U.S. (1 Wheat.) 304, 343–344 (1816); *Ware* v. *Hylton*, 3 U.S. (3 Dall.) 199 (1796) (applying no presumption in case where treaty superseded state criminal law). On the contrary, the Court recognized that "the acts of [a State] must yield to the law of Congress" even when the state law in question was "enacted in execution of acknowledged State power." *Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1, 210–211 (1824). Indeed, during the first several decades of the 20th century the Court recognized a strong generalized presumption *in favor* of preemption. See Mary J. Davis, *Unmasking The Presumption in Favor of Preemption*, 53 S.C. L. REV. 967, 973–983 (2002).

It was not until 1947 that this Court first explicitly recognized the existence of an "assumption" that the "historic police powers of the States" are not superseded when "Congress legislate[s] * * * in [a] field which the States have traditionally occupied" unless Congress makes its intent to do so "clear and manifest." *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). See Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767, 806–807 (1994). At issue in *Rice* was whether Congress had displaced all state law in a particular field. Since *Rice*, the Court has on occasion applied this assumption of nonpreemption (also characterized as the "presumption against preemption") when analyzing claims of "field"

preemption.[3] The Court also has applied the doctrine when interpreting express preemption provisions, see, *e.g.*, *Bates*, 544 U.S. at 449; *Lohr*, 518 U.S. at 485; *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 518 (1992)—although the application of the presumption in that context has not been without controversy. See, *e.g.*, *Engine Mfrs. Ass'n* v. *S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 256 (2004) (noting that "not all Members of this Court agree" on the "application" of the "presumption against pre-emption") (internal quotation marks omitted).[4]

By contrast, the Court almost without exception has avoided reliance on the presumption when addressing claims of conflict preemption.[5] It is true

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[3] See, *e.g.*, *English*, 496 U.S. at 79; *Hillsborough County* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 716 (1985); but see *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238, 247 (1984) (field preemption analysis makes no mention of presumption).

[4] At least two members of the Court reject the presumption's applicability in interpreting the scope of express preemption provisions. See, *e.g.*, *Bates*, 544 U.S. at 457 (Thomas, J., concurring in the judgment in part and dissenting in part); *Cipollone*, 505 U.S. at 544 (Scalia, J., concurring in the judgment in part and dissenting in part); see also *Engine Mfrs. Ass'n*, 541 U.S. at 256.

[5] See, *e.g.*, *Sprietsma* v. *Mercury Marine*, 537 U.S. 51 (2002); *Geier*, 529 U.S. 861; *United States* v. *Locke*, 529 U.S. 89 (2000); *Crosby* v. *Nat'l Foreign Trade Council*, 530 U.S. 363 (2000); *Freightliner Corp.* v. *Myrick*, 514 U.S. 280 (1995); *Gade* v. *Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88 (1992) (plurality); *La. Pub. Serv. Comm'n* v. *FCC*, 476 U.S. 355 (1986); *Wis. Dep't of Indus., Labor & Human Relations* v. *Gould Inc.*, 475 U.S. 282 (1986); *Allis-Chalmers Corp.* v. *Lueck*, 471 U.S. 202 (1985); *Brown* v. *Hotel & Rest. Employees & Bartenders Int'l Union Local 54*, 468 U.S. 491 (1984); *Capital Cities Cable, Inc.* v. *Crisp*, 467 U.S. 691 (1984).

that, in *Hillsborough County* v. *Automated Med. Labs., Inc.*, 471 U.S. 707 (1985), and *California* v. *ARC America Corp.*, 490 U.S. 93 (1989), the Court did preface its conflict preemption analysis with a nod to the presumption. See 471 U.S. at 715–716; 490 U.S. at 101. In neither case, however, did the Court rely on the presumption in the actual analysis itself.[6] Indeed, in *Crosby* v. *National Foreign Trade Council*, 530 U.S. 363 (2000), the Court expressly recognized that the applicability of the presumption in the conflict preemption context remained an open question. See *id.* at 374 n.8 ("We leave for another day a consideration in this context of a presumption against preemption.").

Although the Court has yet to address the issue directly, several recent decisions strongly suggest that the presumption has no relevance in conflict preemption cases.

The Court's most notable recent precedent bearing on this issue is *Geier*, in which the Court held that federal law—a safety standard promulgated under the National Traffic and Motor Vehicle Safety Act of 1966—preempted a state law tort action seeking to impose liability on an automobile manufacturer for failing to install an airbag. See 529 U.S. at 881. Although a state law duty requiring automobile manufacturers to install airbags could plausibly be characterized as a core example of "state police power regulations,"

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[6] At least two post-*Rice* decisions addressing claims of both conflict and field preemption pointedly invoked the presumption only with reference to their field preemption analyses. See, *e.g.*, *Int'l Paper Co.* v. *Ouellette*, 479 U.S. 481, 491 (1987); *Jones* v. *Rath Packing Co.*, 430 U.S. 519, 525 (1977).

Cipollone, 505 U.S. at 518, "in a field which the States have traditionally occupied," *Lohr*, 518 U.S. at 485 (internal quotation marks omitted), the *Geier* majority never even mentioned, let alone applied, any presumption against preemption. See *Geier*, 529 U.S. at 906–907 (Stevens, J., dissenting) ("the Court simply ignores the presumption [against preemption]"). Indeed, rather than apply a presumption against preemption, the *Geier* majority expressly *rejected* the dissent's suggestion that Congress's inclusion of a savings clause in the relevant statute imposed a "special burden" that had to be overcome before preemption could be found. *Id.* at 872–874.

Strongly implying that the presumption against preemption has no relevance to conflict preemption analysis, the *Geier* Court emphasized that it was applying "ordinary," "longstanding," and "experience-proved principles of conflict pre-emption." *Geier*, 529 U.S. at 874. Under these principles, the sole question is whether there is an "actual conflict" between state and federal law; if there is such a conflict, then preemption follows automatically by operation of the Supremacy Clause. *Id.* at 871–872; see also *id.* at 872 (allowing "common-law actions that 'actually conflict' with federal regulations" would thwart "congressionally mandated objectives that the Constitution, through the operation of ordinary pre-emption principles, seeks to protect").

Other recent decisions of the Court are consistent with *Geier*'s apparent rejection of the presumption in conflict preemption cases. For example, in *United States* v. *Locke*, 529 U.S. 89 (2000), the Court, speaking unanimously, termed the presumption "artificial" and declined to invoke it

when analyzing whether certain state regulations conflicted with federal law. *Id.* at 108. And in *Sprietsma* v. *Mercury Marine*, 537 U.S. 51 (2002), the Court made no mention of the presumption when holding that a state law duty to install a propeller guard on a boat motor did not conflict with, and thus was not preempted by, the Coast Guard's decision not to require such guards. See *id.* at 64–68.[7] Rather than rely on the presumption against preemption, the Court based its decision on the Coast Guard's failure to "convey an 'authoritative' message of a federal policy against propeller guards." *Id.* at 67. Absent a federal policy against propeller guards, the Court found, federal law was not "inconsistent with a tort verdict premised on a jury's finding that" a propeller guard was required under the circumstances of the case. *Ibid.* Indeed, echoing *Geier*'s reliance on "ordinary * * * principles of conflict pre-emption," 529 U.S. at 874, the *Sprietsma* Court acknowledged that preemption would have followed automatically had there been a conflict between a federal regulation and a state common-law claim. See *Sprietsma*, 537 U.S. at 65 ("Of course * * * pre-emption would occur."). Thus, although no decision has explicitly held that the presumption against preemption has no role in conflict preemption analysis, the Court's recent opinions have, in apparent recognition of its inapplicability,

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[7] Notably, the Court *did* by contrast allude to the presumption in its analysis (and rejection) of possible *field* preemption under the relevant federal statute. See *Sprietsma*, 537 U.S. at 69 (observing that the "structure and framework" of the federal statute "do not convey a 'clear and manifest' intent * * * to implicitly pre-empt all state common law relating to boat manufacture").

consistently analyzed conflict preemption claims without reference to the presumption.

B. Basic principles preclude application of the presumption against preemption in conflict preemption analysis.

The Court's persistent refusal in recent decisions to invoke the presumption against preemption when analyzing conflict preemption issues is fully consistent with basic principles of constitutional law and statutory construction.

1. Notably, there is no basis in the text of the Constitution for a presumption against preemption. When Congress legislates within the scope of its enumerated powers, the Supremacy Clause renders its enactments "the supreme Law of the Land," U.S. CONST. art. VI, cl. 2, and "invalidates" "'interfer[ing]'" or "'contrary'" state law. *Hillsborough County*, 471 U.S. at 712 (quoting *Gibbons*, 22 U.S. at 211 (Marshall, C.J.)). "[S]ince [the Court's] decision in *M'Culloch* v. *Maryland*, 17 U.S. (4 Wheat.) 316, 427 (1819), it has been settled that state law that conflicts with federal law is without effect." *Cipollone*, 505 U.S. at 516 (internal quotation marks omitted).

Against the backdrop of this well-established framework rooted in the text of the Constitution, the Court has characterized the presumption against preemption as justified by "federalism concerns" (*Lohr*, 518 U.S. at 485), saying it "assur[es] that the federal-state balance will not be disturbed unintentionally by Congress or unnecessarily by the courts." *Jones*, 430 U.S. at 525 (internal quotation marks and citation omitted); see also *Geier*, 529 U.S. at 907 (Stevens, J., dissenting) (presumption is

necessary to allow "the structural safeguards inherent in the normal operation of the legislative process [to] operate to defend state interests from undue infringement").

But this justification is not universally recognized even in the express preemption context. See, *e.g.*, *Cipollone*, 505 U.S. at 544 (Scalia, J.) ("Under the Supremacy Clause, [the Court's] job is to interpret Congress's decrees of pre-emption neither narrowly nor broadly, but in accordance with their apparent meaning.") (citation omitted). More generally, the Supremacy Clause would itself appear to have resolved the invoked "federalism concerns" by establishing an unambiguous and bright-line constitutional rule for how federal and state law are to relate. Indeed, the Court has reiterated that "[u]nder the Supremacy Clause * * * the relative importance to the State of its own law is not material when there is a conflict with a valid federal law, for any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." *Felder* v. *Casey*, 487 U.S. 131, 138 (1988) (internal quotation marks omitted); see also *DeCanas* v. *Bica*, 424 U.S. 351, 357 (1976) ("even state regulation designed to protect vital state interests must give way to paramount federal legislation").[8] Accordingly, to the extent the

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[8] To the extent that the federalism justification for the presumption rests on emanations from the Tenth Amendment, it would appear to be at odds with the decision last Term in *Watters* v. *Wachovia Bank, N.A.*, 127 S. Ct. 1559 (2007), in which the Court squarely held that the Tenth Amendment "is not implicated" in the preemption analysis because "'if a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power

Court "systematically favor[s] one result over another" by applying a presumption against preemption when analyzing preemption questions, it "risk[s] an illegitimate expansion of the judicial function" by "disrupt[ing] the constitutional division of power between federal and state governments, rewrit[ing] the laws enacted by Congress, or both." Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2092 (2000).

As a matter of constitutional history, moreover, there is "no significant support * * * for the conclusion that the [F]ramers intended any * * * presumption to be read into [the Supremacy Clause]." Marin R. Scordato, *Federal Preemption of State Tort Claims*, 35 U.C. DAVIS L. REV. 1, 30 (2001). This is unsurprising given that the Framers' purpose in adopting the Supremacy Clause was "to remedy one of the chief defects in the Articles of Confederation by instructing courts to resolve state-federal conflicts in favor of federal law." David Sloss, *Constitutional Remedies for Statutory Violations*, 89 IOWA L. REV. 355, 402 (2004).

Indeed, the text of the Supremacy Clause, which provides that federal law "shall be the supreme Law of the Land * * * any Thing in the Constitution or Laws of any State to the Contrary notwithstanding" (U.S. Const. art. VI, cl. 2), clearly indicates that the Framers specifically *rejected* a presumption against preemption. The concluding phrase—"any Thing in the Constitution or Laws of any State to the Contrary notwithstanding"—is what the Framers and other eighteenth century lawyers would refer to

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to the States.'" *Id.* at 1573 (quoting *New York* v. *United States*, 505 U.S. 144, 156 (1992)).

as a "*non obstante*" provision. Routinely "used in public and private instruments," such provisions were "intended to preclude, in advance, any interpretation contrary to certain declared objects or purposes." Black's Law Dictionary (6th ed. 1990). As recent historical scholarship explains, the *non obstante* provision was included in the Supremacy Clause to ensure that the presumption against implied repeal, a doctrine already well established by the 18th century, would not thwart the Framers' intent that federal law trump conflicting state law. See Caleb Nelson, *Preemption*, 86 VA. L. REV. 225 (2000). Absent the *non obstante* provision, judges might have been unduly reluctant to declare a state law preempted. "Applying the normal presumption against implied repeals, they might strain the federal law's meaning in order to harmonize it with state law" (*id.* at 255), and thereby frustrate the purpose of the Supremacy Clause. Inclusion of the *non obstante* provision made clear that the presumption against implied repeal should not be applied to protect state law that conflicted with federal law from preemption even when Congress did not expressly declare the relevant state law void.

> [T]he final part of the Supremacy Clause is a global *non obstante* provision. This provision established a rule of construction, telling courts not to apply the traditional presumption against implied repeals in determining whether federal law contradicts state law. Thus, even if a federal statute or treaty did not itself contain a *non obstante* provision, the Supremacy Clause told courts not to strain its meaning in order to harmonize it with state law. As Daniel Webster asserted in his argument in

> *Gibbons v. Ogden*, "[t]he presence or absence of a *non obstante* clause[] cannot affect the extent or operation of the act of Congress," because "[t]he laws of Congress need no *non obstante* clause."

Ibid. Thus, rather than support a presumption *against* preemption, the Constitution's text, if anything, supports a presumption *in favor* of preemption.

2. Despite these unresolved challenges to the presumption's theoretical foundations, the Court's decisions indicate that its invocation may be justified when a court must *infer* congressional intent to determine whether a particular federal statute is preemptive in a particular situation. See *Smiley* v. *Citibank (S.D.), N.A.*, 517 U.S. 735, 744 (1996) (presumption applicable in determining "whether a statute is pre-emptive").

Both express and field preemption analyses may require such an inference in the first instance. Express preemption analysis generally involves judicial interpretation of "explicit statutory language," *English* v. *Gen. Elec. Co.*, 496 U.S. 72, 79 (1990), to determine whether it supplies an "express statement of pre-emptive intent," *Geier*, 529 U.S. at 884, and, if so, to "identify the domain" that Congress "intended" to invalidate by that statement. *Lohr*, 518 U.S. at 484–485 (internal quotation marks omitted).[9] Likewise, courts in field preemption cases

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[9] In such cases, the presumption provides a rule of statutory construction. See, *e.g.*, *Bates*, 544 U.S. at 449 (presumption against preemption imposes "duty" on court "to accept the reading" of statutory preemption provisions "that disfavors preemption"); *Cipollone*, 505 U.S. at 518 ("we must construe

look to the "substantive provisions of the legislation," *Cipollone*, 505 U.S. at 517 (internal quotation marks omitted), when determining whether "Congress intends that federal law occupy a given field." *ARC Am. Corp.*, 490 U.S. at 100.[10]

As the Court has explained, however, "conflict pre-emption is different." *Geier*, 529 U.S. at 884. Conflict preemption does not depend on an inference of congressional intent. Rather, conflict preemption depends on whether a conflict between state and federal law "in fact exists." *Ibid.*[11]

Whether there is an "actual conflict" between a particular federal statute and state law is a "question of the substantive (as opposed to preemptive) *meaning* of [that] statute." *Smiley*, 517 U.S. at 744. Interpreting the federal statute's substantive meaning is an inquiry that "does not bring into play" the presumption against preemption. *Ibid.*[12] Application of a presumption against

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these provisions in light of the presumption against * * * pre-emption").

[10] See also *Hillsborough County*, 471 U.S. at 714 ("The question whether the regulation of an entire field has been reserved by the Federal Government is, essentially, a question of ascertaining the intent underlying the federal scheme.").

[11] See also *Ouellette*, 479 U.S. at 491 (distinguishing judicial "inference" of field preemption, which courts should not undertake "lightly," from situation in which state law "actually conflicts" with federal law) (internal quotation marks omitted).

[12] See also *Brown*, 468 U.S. at 503 ("Where, as here, the issue is one of an *asserted substantive conflict* with a federal enactment, then the relative importance to the State of its own law is not material") (emphasis added; internal quotation marks and alterations omitted); *Fid. Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982) (holding that principles of

preemption "rooted in the concept of federalism," *Geier*, 529 U.S. at 907 (Stevens, J., dissenting), would be particularly inappropriate when courts interpret Congress's substantive enactments because "Congress's chosen level of deference to state interests" is already "reflected in the language that Congress enacts." Nelson, 86 VA. L. REV. at 302. Applying the presumption to interpret federal law narrowly so as to reduce the likelihood that a conflict will be found would in effect "give the political safeguards of federalism a kind of double weight." *Id.* at 300. Accordingly, in a number of cases presenting issues of conflict preemption, this Court instead has applied its standard interpretive methods to arrive at broad constructions of substantive statutory meaning.[13]

Interpreting statutory language to determine its substantive meaning is distinct from, and must not be "confuse[d]" with, inferring whether and to what extent Congress intended to legislate preemptively. *Smiley*, 517 U.S. at 744. It is only in connection with the latter inquiry—which is relevant solely in the express preemption and field preemption contexts—that the presumption against preemption even arguably has a role to play. There is therefore no

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conflict preemption are "not inapplicable * * * simply because [state law at issue] is a matter of special concern to the States").

[13] See, *e.g.*, *Watters*, 127 S. Ct. at 1567 ("We have 'interpreted grants of both enumerated and incidental "powers" to national banks as grants of authority not normally limited by, but rather ordinarily pre-empting, contrary state law.'") (quoting *Barnett Bank of Marion County, N. A.* v. *Nelson*, 517 U.S. 25, 32 (1996)); *Allied-Bruce Terminix Cos.* v. *Dobson*, 513 U.S. 265, 275 (1995) (adopting "broad interpretation" of substantive language determining coverage of Section 2 of the Arbitration Act despite preemptive effect on conflicting state law).

warrant for invoking the presumption, as the Vermont Supreme Court did (see Pet. App. 7a), when analyzing whether state and federal law are in actual conflict.

3. Of course, once a conflict has been identified as a matter of substantive law, the Supremacy Clause requires that "state law [be] nullified to the extent that it actually conflicts with federal law." *Hillsborough County*, 471 U.S. at 713. Indeed, "'[t]he relative importance to the State of its own law is not material when there is a conflict with a valid federal law,' for 'any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield.'" *Felder*, 487 U.S. at 138 (quoting *Free* v. *Bland*, 369 U.S. 663, 666 (1962)). Accord *Geier*, 529 U.S. at 873. If there is an actual conflict between federal and state law, then the preemption of state law "is inescapable and requires no inquiry into congressional design." *Fla. Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. 132, 142–143 (1963).

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There is no basis in this Court's precedents, foundational principles of constitutional law, or the structure of our federal system for a court to invoke a presumption against preemption when analyzing a claim of conflict preemption. Straightforward application of the Supremacy Clause, by contrast, is not only consonant with the Constitution's history and text, but facilitates the realization of Congress's objectives and affords private actors—particularly in regulated fields—an important measure of legal

certainty and predictability.[14] The "day" has come for the Court to "consider[]" the presumption in the conflict preemption context, *Crosby*, 530 U.S. at 374 n.8, and to hold that the presumption has no applicability there.

II. The Decision Below Thwarts Important Federal Policy By Erroneously Denying Preemptive Effect To The FDA's Approval Of Petitioner's Drug Label.

The FDA is the expert federal agency charged by Congress with ensuring that drugs are safe and effective. To that end, the Food, Drug and Cosmetic Act ("FDCA") mandates that drug manufacturers obtain FDA approval to market prescription drugs. The agency decides whether to approve a drug based "on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested *in the labeling*." Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) ("Preemption Preamble") (emphasis added) (citing 21 U.S.C. § 355(d)). Indeed,

> [t]he *centerpiece* of risk management for prescription drugs generally is the labeling which reflects thorough FDA review of the pertinent scientific evidence and

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[14] See *Geier*, 529 U.S. at 874 (noting the "legal uncertainty," and consequent "inevitable systemwide costs," imposed by an unnecessarily "complicated" preemption analysis); cf. *Cent. Bank* v. *First Interstate Bank*, 511 U.S. 164, 188 (1994) (noting "undesirab[ility]" of judicial "decisions made on an ad hoc basis, offering little predictive value") (internal quotation marks omitted).

> communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively. FDA carefully controls the content of labeling for a prescription drug, because such *labeling is FDA's principal tool for educating health care professionals about the risks and benefits of the approved product to help ensure safe and effective use.*

Ibid. (emphasis added); see also *id.* at 3967–3969; New Drug and Antibiotic Regulations, 50 Fed. Reg. 7452, 7470 (Feb. 22, 1985) ("Drug labeling serves as the standard under which FDA determines whether a product is safe and effective."). By imposing state-law tort liability on a drug manufacturer for failure to warn of a drug's dangers, despite the manufacturer's compliance with FDA labeling directives, the decision below "threaten[s] FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs." 71 Fed. Reg. at 3935.

A. State-law failure-to-warn liability conflicts with the FDA's goals of preventing overwarning and patchwork regulation.

The FDA's overarching goal in regulating the warning labels of pharmaceuticals is to strike the right balance between providing sufficient information to drug users and providing too many, or the wrong kind of, warnings. "In setting standards for drug labeling, FDA seeks to encourage the optimal level of use in light of reasonable safety concerns, by requiring scientific evidence that establishes an association between a drug and a

particular hazard before warning of that association on a drug's labeling." Brief of the United States As *Amicus Curiae* In Support of Defendants-Appellees, at 17, *Colacicco* v. *Apotex Inc.*, 521 F.3d 253 (3d Cir. 2008) (No. 06-3107), 2006 WL 5691532 ("FDA *Colacicco* Br.") (citing 21 C.F.R. § 201.80(e)). To achieve that goal, "FDA considers not only complex clinical issues related to the use of the product in study populations, but also important and practical public health issues pertaining to use of the product in day-to-day clinical practice." 71 Fed. Reg. at 3968. Through careful consideration of these factors, "appropriate warnings are drafted that identify established risks while avoiding inadequately substantiated risks, the mention of which could improperly deter use of the drug and result in harm to patients who unnecessarily forego medication." FDA *Colacicco* Br., 2006 WL 5691532, at *6.

In the Preemption Preamble, the FDA emphasized how delicate and important this balance is, and how overwarning can harm patients and interfere with regulatory goals:

> Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use.

71 Fed. Reg. at 3935; *accord* FDA *Colacicco* Br., 2006 WL 5691532, at *16 ("In considering the agency's views on drug labeling, it is critical to understand

that, where warnings are concerned, more is not always better."). Among other dangers, "[e]xaggeration of risk could discourage appropriate use of a beneficial drug." 71 Fed. Reg. at 3935. Moreover, "labeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to 'lose its significance.'" *Ibid.* (quoting 44 Fed. Reg. 37,434, 37,447 (June 26, 1979)). Thus, "State-law attempts to impose additional warnings can lead to labeling that does not accurately portray a product's risks, thereby potentially discouraging safe and effective use of approved products or encouraging inappropriate use and undermining the objectives of the act." *Ibid.*; see also, *e.g.*, Brief for *Amicus Curiae* the United States of America at 23–24, *Motus* v. *Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004) (No. 02-55372), 2002 WL 32303084 (explaining that "[u]nder-utilization of a drug based on dissemination of scientifically unsubstantiated warnings, so as to deprive patients of beneficial, possibly lifesaving treatment, could well frustrate the purposes of federal regulation as much as over-utilization resulting from a failure to disclose a drug's scientifically demonstrable adverse effects").

The courts of appeals have acknowledged the wisdom of preserving FDA primacy in reviewing and approving labeling for products over which it has regulatory authority. When the Third Circuit held in *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004), that the FDA's pre-market approval process for medical devices preempts state common-law claims alleging defective design and manufacture, the court relied upon the agency's conclusion that "'State common law tort actions threaten the statutory framework for the regulation of medical devices,

particularly with regard to FDA's review and approval of product labeling.'" *Id.* at 178 (emphasis added) (quoting the Letter Brief of *Amicus Curiae* the United States of America, at 25, *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (No. 02-4597), 2004 WL 1143720). Similarly, in *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001) (en banc)—a failure-to-warn case involving the labeling of a medical device approved by the FDA—the Eighth Circuit identified

> a number of sound reasons why the FDA may prefer to limit warnings on product labels. Warnings about dangers with less basis in science or fewer hazards could take attention away from those that present confirmed, higher risks. A label with many varied warnings may not deliver the desired information to users. Space on product labeling material is also a factor, and the most effective labels are those with large, bold warnings and a simple design.

Id. at 796.

None of these concerns is likely, however, to motivate—or even be considered by—a jury that is asked to decide a state failure-to-warn claim. All that such a jury would be called upon to determine is whether the content of the defendant's label satisfied the defendant's state-law duty to warn of the *particular* risk allegedly encountered by the *particular* plaintiff. If the jury answers that question in the negative, liability is almost certain to attach, regardless of the potential impact that the addition of that warning might have on *other* warnings with respect to other risks or on *other* patients' ability or willingness to use the product.

This problem is exacerbated by the case-by-case process of common-law adjudication. Later judges or juries cannot reconsider outcomes reached in earlier cases. Thus, a trier of fact cannot deem unnecessary or inappropriate a warning added in response to an earlier verdict. Nor do judges and juries know how many warnings will be vying for limited reader attention.

That is precisely the role of the FDA. As the Eighth Circuit has emphasized, "[i]t would be difficult for a jury focused on a single case to take into account 'the cumulative, systemic effects' of a series of verdicts. In contrast, the FDA possesses a broader perspective." *Brooks*, 273 F.3d at 797 (quoting Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L.J. 2167, 2175 (2000)). Even where a judge or jury is aware of potential overwarning, it can do little to prevent the problem. *See* James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 302 (1990). As this Court recently emphasized in a decision finding preemption in the medical device arena, "tort law[] applied by juries" produces distorted results because it fails to emulate the cost-benefit analysis that an expert agency would employ. *Riegel* v. *Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008) ("A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.").

In light of these widely recognized dangers, the FDA has reasonably determined that state-law "product liability lawsuits have directly threatened

the agency's ability to regulate manufacturer dissemination of risk information for prescription drugs in accordance with the act." 71 Fed. Reg. at 3934. As the agency summarized in the Preemption Preamble:

> State actions are not characterized by centralized expert evaluation of drug regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public—the central role of FDA—sometimes on behalf of a single individual or group of individuals. That individualized reevaluation of the benefits and risks of a product can result in relief—including the threat of significant damage awards or penalties—that creates pressure on manufacturers to attempt to add warnings that FDA has neither approved nor found to be scientifically required. This could encourage manufacturers to propose "defensive labeling" to avoid State liability, which, if implemented, could result in scientifically unsubstantiated warnings and underutilization of beneficial treatments.

Id. at 3935. Only comprehensive, exclusive regulation by an expert agency, such as the FDA, can solve the problem of overwarning by permitting an overall evaluation of risk and a rational decision about what risks are sufficiently serious to warrant inclusion on a label, how those warnings should be phrased, and where they should be placed. This is especially true where, as here, the intended readership consists not of ordinary consumers, but,

under the learned-intermediary doctrine, trained physicians who make judgments based on scientific data and information.

In addition to the danger of overwarning created when states require warnings not approved by the FDA, state regulation via failure-to-warn claims clashes with "the need for national uniformity in product regulation." *Brooks*, 273 F.3d at 797. As the FDA has noted, if judgments under state law were allowed to trump the FDA's assessment of what may appear in drug advertisements, "the public undoubtedly would receive inconsistent information from region to region." *Amicus Curiae* Brief of the United States, at 5, *In re Paxil Litig.*, No. CV 01-07937, 2002 WL 31375497 (C.D. Cal. Oct. 18, 2002), 2001 WL 34883537.

This Court has likewise recognized in the context of another federal labeling regime—the Federal Cigarette Labeling and Advertising Act of 1965—that the national economy can be greatly burdened if manufacturers of a product sold around the country are subjected to "diverse, nonuniform, and confusing * * * labeling and advertising regulations." *Cipollone*, 505 U.S. at 514. Congress, in the legislative history of the Medical Device Amendments to the FDCA, observed that, "if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened." H.R. REP. NO. 853, 45 (1976) (quoted in *Brooks*, 273 F.3d at 797). For these reasons, it was reasonable for the FDA to conclude that,

> [i]f State authorities, including judges and juries applying State law, were permitted to reach conclusions about the safety and

> effectiveness information disseminated with respect to drugs for which FDA has already made a series of regulatory determinations based on its considerable institutional expertise and comprehensive statutory authority, the federal system for regulation of drugs would be disrupted.

71 Fed. Reg. at 3969. Indeed, allowing respondent's claims to proceed would not only risk burdening interstate commerce in prescription drugs, but would also set a precedent that could adversely affect other federally-regulated industries.

B. The decision below misconstrues the relevant FDA regulation.

The decision below—which expressly disregards the considered views of the FDA (see Pet. App. 26a)—rests on a fundamental misunderstanding of the relevant FDA regulation. According to the Vermont Supreme Court, plaintiff's failure-to-warn claim does not conflict "with the FDA's labeling requirements for Phenergan because defendant could have warned against IV-push administration without prior FDA approval, and because federal labeling requirements create a floor, not a ceiling, for state regulation." Pet. App. 6a. The Vermont Supreme Court's decision rests on these false premises.

In fact, Wyeth was not at liberty to change the Phenergan label after its approval by the FDA. As the dissenting opinion explains, the applicable "regulation does not allow manufacturers to simply reassess and draw different conclusions regarding the same risks and benefits already balanced by the FDA." Pet. App. 40a. Rather, that regulation, 21 C.F.R. § 314.70(c), permits a manufacturer to make a

provisional label change *only* if there is newly discovered evidence of a previously unknown or underappreciated risk. As the FDA articulated when proposing § 314.70(c), the rule is designed to "make available important *new* information about the safe use of a drug product." New Drug and Antibiotic Regulations, 47 Fed. Reg. 46622, 46635 (Oct. 19, 1982) (emphasis added); see also Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2849 (Jan. 16, 2008) ("reaffirm[ing]" "the agency's longstanding view" that a drug manufacturer may provisionally change an FDA-approved label without prior agency approval "only to reflect newly acquired information" because "permitting a sponsor to rewrite the labeling for a product following FDA's approval of a product and its labeling would disrupt FDA's careful balancing of how the risks and benefits of the product should be communicated"). In this case, however, there was no new information. The risks associated with arterial blood exposure to Phenergan were fully known by the FDA when it approved the Phenergan label. Indeed, in 1997, at the conclusion of a multiyear administrative review of the Phenergan label, the FDA—with specific reference to the risk of "Inadvertent Intra-arterial Injection"—expressly directed Wyeth to "[r]etain [the] verbiage in [the] current label." Pet. App. 162a. Accordingly, Wyeth was not permitted to change the label without prior FDA approval.

As the FDA explained in the Preemption Preamble, the view (adopted by the court below) that "FDA labeling requirements represent a minimum safety standard" that may be augmented by more stringent state-law requirements is a

"misunderstanding" of the FDCA and the regulations promulgated thereunder. 71 Fed. Reg. at 3934. Because "[o]verwarning, just like underwarning, can similarly have a negative effect on patient safety and public health," requirements imposed by the FDA pursuant to the FDCA "establish both a 'floor' and a 'ceiling.'" *Id.* at 3935. Thus, contrary to the decision below, allowing state law to require an additional warning beyond those required by the FDA would "frustrate the agency's implementation of its statutory mandate." *Id.* at 3934.

It would, moreover, place manufacturers in an impossible position. If subject to state-law failure-to-warn claims, drug manufacturers would be forced to add every conceivable warning to their labels or else risk—as in this case—multimillion dollar tort liability. At the same time, however, because "the determination whether labeling revisions are necessary is, in the end, squarely and solely FDA's under the act" (71 Fed. Reg. at 3934), adding warnings to drug labels without FDA approval would expose manufacturers to administrative enforcement actions (and even criminal prosecution under 21 U.S.C. §§ 331, 333, 352).[15] In some cases,

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[15] Furthermore, in what can fairly be called a Catch-22, adding warnings in response to potential tort liability might even increase a manufacturer's vulnerability to tort claims. As one commentator has suggested, "[i]t seems to be only a matter of time before a plaintiff succeeds in bringing an inadequate warning claim premised on the argument that, although a completely accurate statement of the risk had been provided, the pertinent warning lacked sufficient prominence because it was lost among the clutter of too many other cautionary statements on the label." Lars Noah, *The Imperative to Warn: Disentangling the "Right to Know" From the "Need to Know" About Consumer Product Hazards*, 11 YALE J. ON REG. 293,

manufacturers might respond to this dilemma by withdrawing certain products from the market, thereby diminishing interstate commerce and depriving the public of drugs that the FDA had determined to be safe and effective.

III. The Decision Below Conflicts With This Court's Precedent.

The FDA's interpretation of the FDCA is clear: Because state-law failure-to-warn tort claims interfere with the agency's expert determinations as to the proper balance to be struck in drug labels, "FDA approval of labeling under the act * * * preempts conflicting or contrary State law." 71 Fed. Reg. at 3934.[16] In reaching the opposite conclusion, the Vermont Supreme Court acknowledged the FDA's position, but declined to give it any weight, holding that "the FDA's statement deserves no deference." Pet. App. 26a. The Vermont Supreme Court's failure to defer to the FDA's interpretation of the FDCA is contrary to this Court's precedent.

A. The decision below conflicts with this Court's decisions concerning the deference due executive agencies.

Under the Supremacy Clause, Congress may of course preempt state statutory or common law through federal legislation. See U.S. CONST. art. VI, cl. 2; *Chicago & Nw. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 326–327 (1981). It is also well

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379–380 (1994); see also *id.* at 380 n.435 (describing similar cases in various contexts).

[16] This clear statement is the sort of "'authoritative' message of * * * federal policy" that the *Sprietsma* Court found lacking when it concluded that the state-law claims in that case were not preempted. 537 U.S. at 67.

settled that federal regulations implementing such statutes "have no less pre-emptive effect than federal statutes" themselves. *Fid. Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982).

In the course of delineating the circumstances in which preemption occurs, this Court has held that a federal statute or regulation impliedly preempts any state law (including any state common law) that would "prevent or frustrate the accomplishment of a federal objective." *Geier*, 529 U.S. at 873–874; see also *Locke*, 529 U.S. at 109 (preemption is implied "when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objective of Congress") (internal quotation marks omitted). When, as in the case of the FDA, Congress has delegated authority to an expert federal agency to implement and enforce a federal regulatory scheme, the agency's determination that state law threatens to upset federal objectives "is dispositive * * * unless either the agency's position is inconsistent with clearly expressed congressional intent, or subsequent developments reveal a change in that position." *Hillsborough County*, 471 U.S. at 714–715.

In this instance, the FDA is, pursuant to the FDCA, "the expert Federal agency responsible for evaluating and regulating drugs." 71 Fed. Reg. at 3935. See also 21 U.S.C. § 393(b)(2)(B) (the FDA is to ensure that "human * * * drugs are safe and effective"). As such, it has adopted—in the Preemption Preamble and numerous *amicus* briefs—an authoritative interpretation of the FDCA and the agency's own regulations according to which "FDA approval of labeling under the act * * * preempts conflicting or contrary State law." 71 Fed. Reg. at

3934. That determination—based on the agency's recognition that state-law failure-to-warn claims interfere with its ability to implement finely calibrated labeling decisions under the FDCA—is reasonable and entitled to full deference. "Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, the agency is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,' and, therefore, whether it should be preempted." *Lohr*, 518 U.S. at 496 (citation omitted).

The fact that the FDA has articulated its preemption determination in a regulatory preamble and a series of *amicus* briefs does not diminish the deference owed that determination. As this Court has recognized, an agency's conclusion that federal law preempts state law may properly be communicated in "regulations, *preambles*, interpretive statements and responses to comments." *Hillsborough County*, 471 U.S. at 718 (emphasis added). Similarly, the fact that the "agency's fair and considered judgment on the matter in question" is conveyed "in the form of a legal brief" does not make the agency's view "unworthy of deference." *Auer* v. *Robbins*, 519 U.S. 452, 462 (1997). See also *Geier*, 529 U.S. at 883 (deferring to agency interpretation of ambiguous regulation contained in *amicus* brief submitted in dispute between private parties).

It was, therefore, contrary to this Court's precedent for the Vermont Supreme Court to disregard the FDA's authoritative determination that FDA approval of a drug label preempts state-law tort claims premised on the manufacturer's

failure to provide a warning not required by the FDA.

B. The decision below conflicts with this Court's decisions concerning the effect of savings clauses on implied preemption.

The Vermont Supreme Court's erroneous refusal to defer to the FDA's interpretation of the FDCA rests, in part, on that court's misunderstanding of this Court's preemption jurisprudence.

Recognizing that "deference to an agency's interpretation is appropriate only when a statute is 'silent or ambiguous with respect to the specific issue' the agency has considered," Pet. App. 25a (quoting *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842–843 (1984)), the Vermont Supreme Court disregarded the FDA's interpretation of the FDCA because, in that court's opinion, (a) drug manufacturers can add warnings required by state common-law standards on their own initiative without violating federal regulations, and (b) Congress, in a savings clause, expressly limited implied preemption in the drug context to situations in which compliance with federal and state law is a physical impossibility. See Pet. App. 21a, 26a–28a. But neither premise is correct. The first rests on the court's misunderstanding of 21 C.F.R. § 314.70(c), which—as discussed above—does *not* give drug manufacturers the power to add warnings unilaterally absent new, scientifically valid information. See pages 27–28, *supra*. The second rests on the court's misinterpretation of this Court's implied preemption doctrine.

Section 202 of the 1962 amendments to the FDCA provides that "[n]othing in the amendments

made by this Act * * * shall be construed as invalidating any provision of State law * * * unless there is a direct and positive conflict between such amendments and such provision of State law." Drug Amendments of 1962 § 202, Pub. L. 87-781, 76 Stat. 780, 793 (1962). In the view of the Vermont Supreme Court, this provision "remove[d] from [its] consideration the question of whether common-law tort claims present an obstacle to the purposes and objectives of Congress." Pet. App. 21a. That conclusion, however, is contrary to this Court's precedent.

As this Court made clear in *Geier*, a "saving clause * * * does *not* bar the ordinary working of conflict pre-emption principles." 529 U.S. at 869. Under those well established principles, "'conflicts' that prevent or frustrate the accomplishment of a federal objective and 'conflicts' that make it 'impossible' for private parties to comply with both state and federal law" are equally repugnant to the Supremacy Clause. *Id.* at 873. Accordingly, this Court has steadfastly "refused to read general 'saving' provisions"—such as Section 202—"to tolerate actual conflict *both* in cases involving impossibility *and* in 'frustration-of-purpose' cases." *Id.* at 874 (citations omitted). Because any form of conflict between federal and state law is intolerable to the Supremacy Clause, this Court rejects "attempting to distinguish among types of federal-state conflict for purposes of analyzing whether such a conflict warrants pre-emption in a particular case." *Ibid.*

That, however, is precisely what the Vermont Supreme Court did. It interpreted Section 202 as abrogating state law only when simultaneous

compliance with federal law is impossible, but as preserving state law even if it "present[s] an obstacle to the purposes and objectives of Congress." Pet. App. 21a. Neither the Supremacy Clause nor this Court's precedent permits such a bizarre result.[17]

CONCLUSION

The judgment of the Vermont Supreme Court should be reversed.

Respectfully submitted.

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[17] Notably, the language used by Congress in Section 202 to describe which state laws are preempted—namely state laws that are in "direct and positive conflict" with federal law—is identical to that used by this Court in *Sinnot* v. *Davenport*, 63 U.S. (22 How.) 227, 243 (1859). In that case, this Court held that a state law, which imposed a registration requirement on steamboats beyond that imposed by a federal law meant to facilitate interstate transport, was preempted *even though simultaneous compliance with both state and federal law was not impossible*. Thus, *Sinnot* makes clear that the phrase "direct and positive conflict" encompasses situations in which state law, although not physically incompatible with federal law, nonetheless impedes attainment of the federal statutory objective.

APPENDIX

APPENDIX A

Corporate Members of the Product Liability Advisory Council (as of May 12, 2008)

3M

ACCO Brands Corporation

Altec Industries

Altria Corporate Services, Inc.

American Suzuki Motor Corporation

Andersen Corporation

Anheuser-Busch Companies

Arai Helmet, Ltd.

Astec Industries

BASF Corporation

Bayer Corporation

Beretta U.S.A Corp.

BIC Corporation

Biro Manufacturing Company, Inc.

Black & Decker (U.S.) Inc.

BMW of North America, LLC

Boeing Company

Bombardier Recreational Products

BP America Inc.

Bridgestone Americas Holding, Inc.

Briggs & Stratton Corporation

Brown-Forman Corporation

CARQUEST Corporation

Caterpillar Inc.

Chrysler LLC

Continental Tire North America, Inc.

Cooper Tire and Rubber Company

Coors Brewing Company

Crown Equipment Corporation

Daimler Trucks North America LLC

The Dow Chemical Company

E.I. DuPont De Nemours and Company

Easton-Bell Sports, Inc.

Eaton Corporation

Eli Lilly and Company

Emerson Electric Co.

Engineered Controls International, Inc.

Estee Lauder Companies

Exxon Mobil Corporation

Ford Motor Company

Genentech, Inc.

General Electric Company

General Motors Corporation

GlaxoSmithKline

The Goodyear Tire & Rubber Company

Great Dane Limited Partnership

Harley-Davidson Motor Company

Hawker Beechcraft Corporation

The Heil Company

Honda North America, Inc.

Hyundai Motor America

Illinois Tool Works, Inc.

International Truck and Engine Corporation

Isuzu Motors America, Inc.

Jarden Corporation

Johnson & Johnson

Johnson Controls, Inc.

Joy Global Inc., Joy Mining Machinery

Kawasaki Motors Corp., U.S.A.

Kia Motors America, Inc.

Koch Industries

Kolcraft Enterprises, Inc.

Komatsu America Corp.

Kraft Foods North America, Inc.

Leviton Manufacturing Co., Inc.

Lincoln Electric Company

Magna International Inc.

Mazda (North America), Inc.

Medtronic, Inc.

Merck & Co., Inc.

Michelin North America, Inc.

Microsoft Corporation

Mine Safety Appliances Company

Mitsubishi Motors North America, Inc.

Mueller Water Products

Nintendo of America, Inc.

Niro Inc.

Nissan North America, Inc.

Nokia Inc.

Novartis Consumer Health, Inc.

Novartis Pharmaceuticals Corporation

Occidental Petroleum Corporation

PACCAR Inc.

Panasonic

Pfizer Inc.

Porsche Cars North America, Inc.

PPG Industries, Inc.

Purdue Pharma L.P.

Putsch GmbH & Co. KG

The Raymond Corporation

Remington Arms Company, Inc.

Rheem Manufacturing

RJ Reynolds Tobacco Company

Sanofi-Aventis

Schindler Elevator Corporation

SCM Group USA Inc.

Shell Oil Company
The Sherwin-Williams Company
Smith & Nephew, Inc.
St. Jude Medical, Inc.
Subaru of America, Inc.
Synthes (U.S.A.)
Terex Corporation
Textron, Inc.
TK Holdings Inc.
The Toro Company
Toshiba America Incorporated
Toyota Motor Sales, USA, Inc.
TRW Automotive
UST (U.S. Tobacco)
Vermeer Manufacturing Company
The Viking Corporation
Volkswagen of America, Inc.
Volvo Cars of North America, Inc.
Vulcan Materials Company
Watts Water Technologies, Inc.
Whirlpool Corporation
Wyeth
Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
Zimmer, Inc.